

ANDERSON EXHIBIT 6A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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UNITED STATES OF AMERICA)

Ex Rel)

VEN-A-CARE OF THE)
FLORIDA KEYS, INC.,)
a Florida Corporation,)
by and through its principal)
officers and directors,)
ZACHARY T. BENTLEY and)
T. MARK JONES,)

Plaintiff,)

v.)

ABBOTT LABORATORIES, INC.;)
ALPHARMA, INC.;)
ALPHARMA USPD, INC. f/k/a)
BARRE-NATIONAL, INC.;)
APOTHECON, INC.;)
AVENTIS PHARMACEUTICALS, INC.;)
AVENTIS BEHRING LLC;)
BARR LABORATORIES, INC.;)
BARR PHARMACEUTICALS, INC.;)
BARRE PARENT CORP.;)
BOEHRINGER INGELHEIM, CORP.;)
BOEHRINGER INGELHEIM)
PHARMACEUTICALS, INC.;)
BOEHRINGER INGELHEIM)
INTERNATIONAL GmbH;)
BOEHRINGER INGELHEIM)
AUSLANDBETEILIGUNGS GmbH;)
BRISTOL-MYERS SQUIBB)
COMPANY;)
C.H. BOEHRINGER SOHN;)
DEY, INC.;)
DURAMED RESEARCH, INC.;)
EM PHARMA, INC.;)
EMD PHARMACEUTICALS, INC.;)
ETHEX CORPORATION;)

U.S. DISTRICT COURT
DISTRICT OF MASS.

CIVIL ACTION NO. 00 CV10698 MEL

FILED IN CAMERA AND
UNDER SEAL

THIRD AMENDED COMPLAINT

CIVIL ACTION NO. 00 CV10698 MEL

GENEVA PHARMACEUTICALS, INC.;)	
GLAXO WELLCOME, INC.;)	
GLAXOSMITHKLINE PLC;)	
HARVARD DRUG GROUP, LLC;)	For Money Damages and Civil
HOECHST MARION ROUSSEL, INC.;)	Penalties Under the False Claims
HOSPIRA, INC.;)	Act 31 U.S.C. §§3729-3732
IVAX CORPORATION ;)	
IVAX PHARMACEUTICALS, INC.;)	
KV PHARMACEUTICAL COMPANY;)	
LIPHA, S.A.;)	
MAJOR PHARMACEUTICALS;)	
MERCK-LIPHA, S.A.;)	
MERCK KGaA;)	
MYLAN PHARMACEUTICALS, INC.;)	
MYLAN LABORATORIES, INC.;)	
PAR PHARMACEUTICAL)	
COMPANIES, INC.;)	
PAR PHARMACEUTICALS, INC.;)	
PHARMA-INVESTMENT LIMITED;)	
PURDUE PHARMA L.P.;)	
PURDUE PHARMA, INC.;)	
PURDUE FREDERICK COMPANY;)	
PUREPAC PHARMACEUTICAL CO.;)	
QUALITEST PHARMACEUTICALS, INC.;)	
ROXANE LABORATORIES, INC.;)	
SANDOZ, INC.;)	
SCHEIN PHARMACEUTICAL, INC.;)	
SCHERING CORPORATION;)	
SCHERING-PLOUGH CORP.;)	
SMITHKLINE BEECHAM CORP.;)	
TEVA PHARMACEUTICALS, USA;)	
UDL LABORATORIES, INC.;)	
WARRICK PHARMACEUTICALS CORP.;)	
WATSON PHARMACEUTICALS, INC.;)	
WATSON LABORATORIES;)	
and ZENITH GOLDLINE)	
PHARMACEUTICALS, INC.,)	
)	
Defendants.)	

CIVIL ACTION NO. 00 CV10698 MEL

THIRD AMENDED COMPLAINT
FOR MONEY DAMAGES AND CIVIL PENALTIES UNDER THE FALSE
CLAIMS ACT 31 U.S.C. §§3729-3732

COMES NOW, the UNITED STATES OF AMERICA ("UNITED STATES" or "GOVERNMENT"), by and through VEN-A-CARE OF THE FLORIDA KEYS, INC. ("VEN-A-CARE" or "the Relator"), and its principal officers and directors, ZACHARY T. BENTLEY and T. MARK JONES, and by and through the undersigned attorneys on behalf of the UNITED STATES and on the Relator's own behalf and brings this action against ABBOTT LABORATORIES, INC.; ALPHARMA, INC.; ALPHARMA USPD, INC. f/k/a BARRE-NATIONAL, INC.; APOTHECON, INC.; AVENTIS PHARMACEUTICALS, INC.; AVENTIS BEHRING LLC; BARR LABORATORIES, INC.; BARR PHARMACEUTICALS, INC.; BARRE PARENT CORP.; BOEHRINGER INGELHEIM, CORP.; BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.; BOEHRINGER INGELHEIM INTERNATIONAL GmbH; BOEHRINGER INGELHEIM AUSLANDBETEILIGUNGS GmbH; BRISTOL-MYERS SQUIBB COMPANY; C.H. BOEHRINGER SOHN; DEY, INC.; DURAMED RESEARCH, INC.; EM PHARMA, INC.; EMD PHARMACEUTICALS, INC.; ETHEX CORPORATION; GENEVA PHARMACEUTICALS, INC.; GLAXO WELLCOME, INC.; GLAXOSMITHKLINE PLC; HARVARD DRUG GROUP, LLC; HOECHST MARION ROUSSEL, INC.; HOSPIRA, INC. IVAX CORPORATION; IVAX PHARMACEUTICALS, INC.; KV PHARMACEUTICAL

CIVIL ACTION NO. 00 CV10698 MEL

COMPANY; LIPHA, S.A.; MERCK-LIPHA, S.A.; MERCK KGaA; MAJOR PHARMACEUTICALS; MYLAN PHARMACEUTICALS, INC.; MYLAN LABORATORIES, INC.; PAR PHARMACEUTICAL COMPANIES, INC.; PAR PHARMACEUTICALS, INC.; PHARMA-INVESTMENT LIMITED; PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; PURDUE FREDERICK COMPANY; PUREPAC PHARMACEUTICAL CO.; QUALITEST PHARMACEUTICALS, INC.; ROXANE LABORATORIES, INC.; SANDOZ, INC.; SCHEIN PHARMACEUTICAL, INC.; SCHERING CORPORATION; SCHERING-PLOUGH CORP.; SMITHKLINE BEECHAM CORP.; TEVA PHARMACEUTICALS, USA; UDL LABORATORIES, INC.; WARRICK PHARMACEUTICALS CORP.; WATSON PHARMACEUTICALS, INC.; WATSON LABORATORIES; and ZENITH GOLDLINE PHARMACEUTICALS, INC., (sometimes referred to collectively as "DEFENDANTS"), for money damages and civil penalties arising out of the DEFENDANTS' violations of the Federal False Claims Act ("False Claims Act" or the "Act") 31 U.S.C., §§3729-3732.

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**SECTION NO. 1
SUMMARY OF THE ACTION**

1. This is an action for damages, treble damages, restitution, civil penalties, pre-judgment interest and equitable relief, and for attorneys' fees and expenses of the Relator, against the DEFENDANTS for violations of the False Claims Act as set out in Counts I through X. The violations arise from DEFENDANTS' actions which caused Medicare and the State Medicaid Programs to pay grossly inflated prices for DEFENDANTS' prescription

drugs. This Third Amended Complaint encompasses all the drugs identified in **Exhibits "1" and "2"** and those that may be added as amendments to this action in the future.

2. The Medicare and State Medicaid Programs pay claims for the prescription drugs specified herein only if three distinct requirements are met. First, the pharmaceutical drug manufacturer must make price and cost information about the prescription drug available to price and cost publishing compendia, including First DataBank, Medi-span and Red Book. Second, the program must elect to cover the prescription drug when medically necessary. Third, the physician, pharmacy or other health care provider who purchases the prescription drug must confirm that it was administered or dispensed to an eligible person covered by the applicable program. In some cases, most notably that of the Texas Medicaid Program, pharmaceutical manufacturers must report costs and prices directly to the state program to satisfy the price disclosure requirement.

3. This false claims action reveals an intentional scheme by DEFENDANTS to arrange financial inducements aimed at physicians (including physicians such as oncologists and infectious disease physicians, for example), clinics, ESRD Dialysis facilities and pharmacies to increase sales of DEFENDANTS' prescription drugs which are reimbursed by Medicare and the State Medicaid Programs (sometimes collectively referred to herein as "Medicare/Medicaid"). The particular prescription drugs at issue here are hereinafter referred to as the "specified drugs" and are listed in the attached **Exhibits "1" and "2"**. The DEFENDANTS reported or caused the reporting of false price and cost information to price publishing compendia, including Red Book, Medi-Span and First

DataBank, which resulted in the reporting of inflated Average Wholesale Price ("AWP"), Direct Price ("DP") and Wholesaler Acquisition Cost ("WAC") information to Medicare and the States' Medicaid Programs. The Defendants also reported such false price and cost information directly to State Medicaid Programs including that of Texas. The DEFENDANTS, participating in what amounts to a kickback scheme, created financial inducements by falsely inflating their reports of the price and cost information for the specified drugs and by offering concealed financial remuneration, in the form of free goods, discounts, direct monetary payments and rebates to customers, thus causing Medicare/Medicaid to pay inflated reimbursements to the DEFENDANTS' customers such as physicians, clinics, pharmacies and ESRD facilities. The DEFENDANTS' customers that submitted claims for reimbursement to Medicare and/or Medicaid for the specified drugs and provided the covered drug to the drug recipient are collectively referred to as "the Providers". The DEFENDANTS thus knowingly concealed from Medicare/Medicaid the prices generally and currently available in the marketplace and caused Medicare/Medicaid to use falsely inflated price reports when determining reimbursement amounts. The DEFENDANTS were fully aware of the Medicare and Medicaid reimbursement methodologies and knew that Medicare/Medicaid used the DEFENDANTS' reported drug prices and costs in establishing reimbursement amounts. Each DEFENDANT, had it so chosen, could have reported prices and costs for the specified drugs that were fairly and reasonably representative of the prices generally and currently available in the marketplace. The DEFENDANTS were also free to elect not to report

prices and thus not have their drugs covered by Medicare/Medicaid. Rather than choose either of these options, each of the DEFENDANTS has knowingly opted to report inflated prices and costs for the express purpose of creating an inflated spread between the resulting Medicare/Medicaid reimbursement amounts and the prices generally and currently available in the marketplace to Providers. The "Spread" is the difference between the purchase price and the amount reimbursed by Medicare/Medicaid. The inflated Spread caused Providers to purchase the specified drugs because it enabled them to receive inflated reimbursement amounts from the Medicaid and/or Medicare programs.

4. The DEFENDANTS were fully aware that the Medicare and State Medicaid Programs were required by their reimbursement policies to use the drug prices and costs reported by the drug manufacturers, including the DEFENDANTS, in calculating reimbursement amounts.

5. Additionally, some of the DEFENDANTS falsely identified their drugs to the federal government as non-innovator drugs for purposes of the Medicaid Rebate Program, when in truth they were innovator drugs. This deception enabled them to falsely pay a lesser rebate pursuant to the Medicaid Rebate Program, and thus defeated the purpose of that program, which was to permit the federal and state governments to receive the benefit of the drug manufacturers' lowest prices to commercial customers.

6. Damages are determined based on the inflated reimbursement amounts and any appropriate adjustments due to make the United States whole as intended by the Medicaid Rebate Program.

7. As a result of DEFENDANTS' fraudulent and illegal acts alleged herein, DEFENDANTS have substantially increased the expense to the taxpayer of the federal and state health programs and directly contributed to the soaring cost of providing prescription drugs for the nation's elderly and poor.

A. THE DEFENDANTS' FRAUD PERTAINED TO TWO CATEGORIES OF PRESCRIPTION DRUGS: 1) DRUGS REIMBURSED SOLELY BY MEDICAID; AND 2) DRUGS REIMBURSED BY BOTH MEDICAID AND MEDICARE

8. All fifty states have chosen to provide prescription drug coverage pursuant to Medicaid, the federal medical assistance program for the poor, which the federal and state governments jointly fund and which each state administers pursuant to federal statutes, regulations and guidelines. Additionally, the Medicare Program (which covers certain outpatient medical care for those over age 65, persons who are disabled and persons who have end stage renal disease), provides coverage for certain drugs which generally cannot be taken by mouth or self-administered and for a small number of oral drugs, including some chemotherapy and anti-emetic drugs.

9. The drugs in this case are of two types: those that are reimbursed only by the State Medicaid Programs and those that are reimbursed by both the State Medicaid Programs and by the Medicare Program. The first type, "specified retail pharmacy drugs," are virtually all taken orally or self-administered through a hand-held inhaler and are typically dispensed by retail pharmacies. The second type, hereinafter sometimes referred to as the "specified Medicare/Medicaid drugs", are reimbursed by both the State Medicaid Programs and by Medicare. These drugs are typically prescribed for the treatment of

illnesses such as respiratory diseases, severe infections, cancer and rheumatoid arthritis. They are generally available only through a hospital, physician, dialysis facility or pharmacy. Many of the specified Medicare/Medicaid drugs are commonly referred to as "chemotherapy," "chemo" or "oncology" drugs. The other specified Medicare/Medicaid drugs at issue include, but are not limited to, intravenous antibiotics, oral anti-emetics and drugs used for inhalation therapy.

10. The pricing fraud allegations of this action pertain only to the Medicare/Medicaid reimbursement for the ingredient costs of the prescription drugs at issue herein and not to reimbursement for the administering or dispensing such drugs. Medicare and Medicaid reimbursement for ingredient costs is separate and distinct from reimbursement for administering or dispensing the drugs and involves separate payments and different methodologies.

B. DRUG MANUFACTURERS' FALSE PRICE AND COST REPRESENTATIONS INVOLVING RETAIL PHARMACIES AND THE STATE MEDICAID PROGRAMS

11. The DEFENDANTS falsely represented the prices that they charged wholesalers and/or the prices paid by Providers for the specified retail pharmacy drugs in order to cause State Medicaid Programs to pay claims in excessive amounts. All State Medicaid Programs are funded jointly by the United States and the states, with the United States paying at least 50% of the cost of each state's program. The State Medicaid Programs are required to pay drug reimbursement claims in amounts that do not exceed

the drug's Estimated Acquisition Cost ("EAC") to the pharmacy submitting the claim. 42 CFR §447.331. The DEFENDANTS knew that each of the States' Medicaid Programs had implemented a mechanism to estimate the acquisition cost of prescription drugs to a pharmacy. Most states (hereinafter sometimes referred to as "AWP STATES") based their estimates on the DEFENDANTS' representation of the AWP of their drugs. Some States based their estimate on the DEFENDANTS' representation of the prices they charged wholesalers for the specified drugs, sometimes referred to as "WAC," or as "price to wholesaler." Some States based their estimates on the DEFENDANTS' representations of their prices they charged Providers directly for the Specified Drugs sometimes referred to as "DP" or direct price. Attached as **Composite Exhibit "3"** is a chart showing the reimbursement methodologies used by each state from 1994 - 2004. In the case of the Specified Retail Pharmacy Drugs, the DEFENDANTS falsely inflated their reports of the drug prices and costs with the hope that Medicaid pharmacy Providers would be paid excessive amounts and thus choose their specified retail pharmacy drugs over competing brand and generic versions. The DEFENDANTS' false price representations were made directly to the States by the DEFENDANTS and through one or more of several recognized drug price publishing compendia including First DataBank, Medical Economics and Medi-Span. Those publications assemble drug price data, which the State Medicaid Programs use to establish reimbursement amounts.

12. For many of their drugs, the DEFENDANTS reported prices and costs that were based upon a fair and reasonable review of their business records and other

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information available to them, and the States' Medicaid Programs were thus able to accurately estimate acquisition costs when paying claims for those drugs.

13. The DEFENDANTS caused the States to estimate and use inflated acquisition costs for reimbursement purposes and thus caused an inflated spread between the reimbursement set and the prices generally and currently available to Providers. The inflated Spread directly benefitted the DEFENDANTS, because it provided an incentive for Providers to order the DEFENDANTS' Specified Drugs instead of their competitors' drugs. The DEFENDANTS thus duped the State Medicaid Programs into paying claims for the specified drugs at inflated amounts in an effort to maintain and increase the DEFENDANTS' sales.

14. The DEFENDANTS' wrongful exploitation of the State Medicaid Programs caused the UNITED STATES and the State Medicaid Programs to incur single damages in excess of Ten Million Dollars. The UNITED STATES and the States' Medicaid Programs are entitled to recover three times their damages plus up to Eleven Thousand Dollars per false claim, together with interest, costs and attorneys' fees.